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Assistant Commissioner for Patents

File No. 16051-10US

REMARKS

Claims 1-36 are pending in the application. Claim 1 as now amended and original claims 2-4, 6-7 and 10-17 are under examination. Claims 5, 8, 9 and 18-36 are currently withdrawn.

Applicants wish to point out that no new matter is being hereby introduced in the claim. The specification at paragraph [0057] has been amended to clarify the intended definition of a non-sequence complementary mode of action. One skilled in the art would acknowledge that a non-sequence complementary mode of action inherently means that the anti-viral activity occurs principally by a sequence-independent mode of action. The amendment made to paragraph [0057] does not introduce any new subject matter.

Claim rejections - 35 U.S.C. § 132(a), 102(a & e) and 103(a)

The amendment submitted April 24, 2006, has been rejected under 35 U.S.C. § 132(a) because it introduced new matter into the disclosure. The Examiner mentioned that the added material, which is not supported by the original disclosure, needs to be cancelled. More specifically, the added material is as follows: "the oligonucleotide binds to one or more viral proteins, wherein said viral protein is different from a retroviral nucleocapsid protein, meaning that the viral component is not a retroviral nucleocapsid protein". Upon cancellation of the new matter of amended claim 1, rejection of claims 1-4, 6-7 and 10-17 under 35 U.S.C. § 102(a & e) as being anticipated, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over Rein *et al.* (US Patent No 6,316,190) will be reinstated.

In order to overcome this rejection, Applicants wish to respectfully point out to the Examiner that it is believed that the amendment of claim 1, submitted on April 24, 2006, did not introduce new matter. On the contrary, as supported by paragraph [0044] of the present

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description, the Applicants were well aware of the document of Rein *et al.* Thus, since Applicants knew about the teaching found in the identified document, amendment of claim 1 had the purpose of disclaiming the teaching of Rein *et al.* since it was not new and inventive. Applicants are well aware that in order for an invention to be patentable, it must be new as defined in the patent law, which provides that an invention cannot be patented if: "(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent," or "(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country more than one year prior to the application for patent in the United States..." Thus, by specifying that "the oligonucleotide binds to one or more viral proteins, wherein said viral protein is different from a retroviral nucleocapsid protein, meaning that the viral component is not a retroviral nucleocapsid protein", Applicants are claiming subject matter that is believed to be new and inventive.

Further, Applicants wish to submit that claim 1 was additionally amended to specify that the binding of the oligonucleotide of the present invention to said viral component occurs principally by a sequence independent mode of action. On the contrary, Rein *et al.* teaches assays where target molecules are assessed for their ability to inhibit binding of retroviral nucleocapsid proteins to selected nucleic acids (oligonucleotides). In the assays, retroviral nucleocapsid proteins, oligonucleotides comprising a substance which binds to a retroviral nucleocapsid protein with high affinity, and a target molecule are mixed, and the inhibitory effect on nucleocapsid-oligonucleotide binding is measured. Rein *et al.* also discloses additional oligonucleotides which bind to nucleocapsid proteins. Nowhere in Rein *et al.* is it disclosed or suggested assays for screening of compounds that alters binding of an oligonucleotide to at least one viral component that is not a retroviral nucleocapsid protein and wherein the binding of said oligonucleotide to said

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viral component occurs principally by a sequence independent mode of action as claimed in the present application. Rein *et al.* invention reveals that specific single stranded nucleic acid sequences (both RNA and DNA) bind nucleocapsid proteins. A person skilled in the art, following the teaching found in Rein *et al.*, would acknowledge that the specific single stranded nucleic acid sequences (both RNA and DNA) are preferentially sequences rich in "GT" or "GU" (in the case of an RNA sequence). It is clearly stated in Rein *et al.*, in column 32, lines 64-67, that "*a large fraction of the hydrophobic interaction of NC with d(TG)₄ (SEQ ID NO: 6) evidently involves the exocyclic amino group on guanine.*" Thus, contrary to the present application which is encompassing an oligonucleotide binding to a viral component occurring principally by a sequence independent mode of action, the oligonucleotides taught in Rein *et al.* have specific single stranded nucleic acid sequences and are sequences rich in guanine in order to bind to retroviral nucleocapsid proteins. It is believed that the oligonucleotides of Rein *et al.* are not binding by a sequence independent mode of action, as defined in paragraph [0057] of the present description. Further, it is believed that the oligonucleotides disclosed in Rein *et al.* do not meet the criterion of any of the 3 tests outlined in Example 10 of the present description. In addition, Rein *et al.* teaches assays where target molecules are assessed for their ability to inhibit binding of retroviral nucleocapsid proteins to selected nucleic acids (oligonucleotides) by incubating first the oligonucleotides with purified retroviral nucleocapsid protein (see column 12 in Rein *et al.*). Nowhere is it taught, or suggested or claimed in the present application that in the claimed method of screening to identify a compound that alters binding of an oligonucleotide to at least one viral component, the oligonucleotide of the present invention need to be incubated with purified nucleocapsid. In view of the above, reconsideration and withdrawal of the Examiner's rejections is earnestly requested.

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Assistant Commissioner for PatentsClaim rejections - 35 U.S.C. § 112

Claims 1-4, 6-7 and 10-17 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written requirement. The Examiner mentioned that amendment of claim 1 introduces new matter as the claims recited the limitation "wherein said viral protein is different from a retroviral nucleocapsid protein, meaning that the viral component is not a retroviral nucleocapsid protein" and thus must be cancelled. In order to overcome this rejection, Applicants respectfully submit that it is believed that the amendment of claim 1 submitted on April 24, 2006, did not introduce new matter. On the contrary, as supported by paragraph [0044] of the present description, the Applicants were well aware of the document of Rein *et al.* Thus, since Applicants knew about the teaching found in the identified document, amendment of claim 1 had the purpose of disclaiming the teaching of Rein *et al.* since it was not new and inventive. Thus, by specifying that "the oligonucleotide binds to one or more viral proteins, wherein said viral protein is different from a retroviral nucleocapsid protein, meaning that the viral component is not a retroviral nucleocapsid protein", Applicants are claiming subject matter that is believed to be new and inventive. In view of the arguments presented hereinabove, reconsideration and withdrawal of Examiner's rejection is earnestly solicited.

It is submitted, therefore, that the claims are in condition for allowance.

No additional fees are believed to be necessitated by this amendment. Should this be in error, authorization is hereby given to charge Deposit Account No. 19-5113 for any underpayment or to credit any overpayment.

In the event that there are any questions concerning this Response, or the application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of the application may be expedited.

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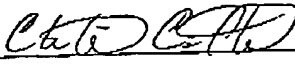
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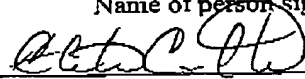
Respectfully,

Date: October 26, 2006

By:


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Date